Title:	**Investigator terminology**	
Version:	02	
Effective date:	01-AUG-2011	
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Investigator terminology

The terminology and definitions for the various investigator roles are often different between organizations. This policy represents the terms and definitions for investigator roles used in HOVON sponsored trials.

Principal Investigator (PI)

Each trial has only one principal investigator (PI) The working group initiating the trial appoints the PI.

The PI is coordinating the trial on behalf of HOVON and bears executive responsibility for the overall conduct of the trial.

The PI is the primary contact for other parties involved in the trial, such as companies and the HOVON Data Center.

For a more detailed description of PI tasks refer to HOVON policy “PI responsibilities and qualifications”.

Coordinating investigator (CI)

For each country other than the Netherlands participating in the trial there is one coordinating investigator (CI).

If sites from other countries are participating under affiliation of a study group, that study group appoints the coordinating investigator. If the country is not represented as part of a study group, the HOVON working group initiating the trial will appoint the coordinating investigator.

The coordinating investigator is coordinating the conduct of the trial in the country he/she is appointed to.

The coordinating investigator is the primary contact in his country for the PI and other parties involved in the trial regarding country-specific issues.

At the start of each trial the Principal Investigator should discuss in detail which tasks are delegated to the coordinating investigator. For guidance in this discussion please refer to the HOVON policy “Collaboration in international trials”.

Co-investigator

The trial has at least one and at the most two co-investigators for HOVON. The co-investigator(s) representing HOVON are appointed by the working group initiating the trial.

The trial also has at least one and at the most two co-investigators for each other study group involved in the trial, or for each country if the country is not represented as part of a study group. In the first case the co-investigator is appointed by the study group, in the second case by the coordinating investigator for the country.

A co-investigator for HOVON cooperates with the PI in the coordination of the trial. The co-investigator for HOVON can assume all tasks and responsibilities of the PI if the PI is not available. The co-investigator is the “deputy-PI”.

A co-investigator for another study group or country cooperates with the coordinating investigator in the coordination of the trial in the affiliated sites. The co-investigator can assume all tasks and responsibilities of the coordinating investigator if the coordinating investigator is not available. The co-investigator is the “deputy-coordinating investigator”.

Local investigator

Each site participating in the trial has only one local investigator.

The local investigator coordinates and is responsible for the conduct of the trial at his/her site, as described in chapter 4 of the ICH-GCP guideline.

Sub-investigator

At each site participating in the trial there may be one or more sub-investigators.

The local investigator of the site appoints the sub-investigator.

The sub-investigator executes trial related tasks that require medical qualifications, such as obtaining informed consent and treatment of patients. Tasks delegated to a sub-investigator should be recorded on a site distribution of responsibilities log (also known as site signature log).